

Translation

PATENT COOPERATION TREATY

PCT/EP2003/006942



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 24550PCT drr/ba	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/006942	International filing date (day/month/year) 30 June 2003 (30.06.2003)	Priority date (day/month/year) 22 July 2002 (22.07.2002)
International Patent Classification (IPC) or national classification and IPC A61M 15/00		
Applicant VON SCHUCKMANN, Alfred		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 17 February 2004 (17.02.2004)	Date of completion of this report 06 July 2004 (06.07.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/006942

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
pages \_\_\_\_\_ 1-28 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
pages \_\_\_\_\_ 1-29 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the drawings:  
pages \_\_\_\_\_ 1/13-13/13 \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

See supplemental sheet.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. \_\_\_\_\_

## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX IV.3**Lack of unity of invention**

1. The examiner has determined that this international application contains multiple (groups of) inventions that are not linked by a single general inventive concept (PCT Rule 13.1), as follows:

## I. Claims 1-21

manually actuated inhalator for powdered substances, the air flow volume resulting from the movement of the piston amounting to more than hundred times but less than six hundred times the volume of the metering chamber.

## II. Claims 22-29

manually actuated inhalator for powdered substances in which the metering chamber is open towards the substance reservoir in the initial position of the shaft.

2. The reasons therefor are as follows.

The common features of the preamble of claims 1 and 22 are known from document D1 (see figure 3 and the abstract, member of the patent family of DE19963946, cited on page 2, line 5, of the application).

Claim 1 further defines the design of the metering chamber in order to improve the membrane service life (see page 2, lines 18-19).

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: **BOX IV.3**

In claim 22, the metering chamber is designed in order to improve metering and the administration of powder doses (see page 7, lines 5-15).

Consequently, claims 1 and 22 solve different problems and do not have any common special technical features within the meaning of PCT Rule 13.2.

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**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-29	YES
	Claims		NO
Inventive step (IS)	Claims	1-29	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-29	YES
	Claims		NO

**2. Citations and explanations**

1. This report makes reference to the following documents:

D1: WO 01/15760 A (SCHUCKMANN ALFRED VON), 8 March 2001

D2: EP-A-0 652 022 (TEIJIN LTD), 10 May 1995

**Claims 1-21:**

2. Document D1 is considered to constitute the prior art closest to the subject matter of claim 1 and discloses (the references in parentheses are to that document):

a manually actuated inhalator for powdered substances having a metering chamber (figure 5a), the base of the metering chamber being formed by an air-permeable membrane (47, figure 5a).

- 2.1 The subject matter of claim 1 therefore differs from the known manually actuated inhalator for powdered substances described in D1 in that the air flow volume resulting from the movement of the piston amounts to more than hundred times but less than six

hundred times the volume of the metering chamber.

- 2.2 The subject matter of claim 1 is therefore novel (PCT Article 33(2)).
- 2.3 The present invention can therefore be considered to address the problem of designing the metering chamber in such a way that stronger stresses upon the air-permeable membrane can be avoided.
- 2.4 The solution to this problem, as proposed in claim 1 of the present application, involves an inventive step (PCT Article 33(3)) for the following reasons:
- D1 does not indicate the exact design of the metering chamber, and D2 works according to a different principle, so that a person skilled in the art would not be guided to the solution as per claim 1.
- 2.5 Claims 2-21 are dependent on claim 1 and therefore also meet the PCT novelty and inventive step requirements.

**Claims 22-29:**

3. Document D1 is considered to constitute the prior art closest to the subject matter of claim 22 and discloses (the references in parentheses are to that document):

a manually actuated inhalator for powdered substances having a metering chamber (figure 5a), the base of the metering chamber being formed by an air-permeable membrane (47, figure 5a).

- 3.1 The subject matter of claim 22 therefore differs from the known manually actuated inhalator for powdered substances described in D1 in that the metering chamber is open towards the substance reservoir in the initial position of the shaft.
- 2.2 The subject matter of claim 22 is therefore novel (PCT Article 33(2)).
- 2.3 The present invention can therefore be considered to address the problem of designing the metering chamber in such a way that metering and administration of powder doses are improved (see page 7, lines 5-15).
- 2.4 The solution to this problem, as proposed in claim 1 of the present application, involves an inventive step (PCT Article 33(3)) for the following reasons:
- In D1, the filling path that leads to the metering chamber is closed towards the substance reservoir (SV) in the initial position of the shaft (15), and therefore the powdered substance cannot enter the metering chamber in this initial position. D2 is technically further removed. A person skilled in the art would therefore not arrive at the subject matter of claim 22, in the light of the problem and of documents D1 and D2.
- 2.5 Claims 23-29 are dependent on claim 1 and therefore also meet the PCT novelty and inventive step requirements.